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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,453	09/13/2000	Steven M. Ruben	PZ038P1	8927

22195 7590 06/18/2002  
HUMAN GENOME SCIENCES INC  
9410 KEY WEST AVENUE  
ROCKVILLE, MD 20850

EXAMINER
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MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/18/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/661,453**

Applicant(s)  
**Ruben et al.**

Examiner  
**Ardin Marschel**

Art Unit  
**1631**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Mar 28, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above, claim(s) 1-10, 13-15, and 17-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11, 12, 16, and 24-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-73 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1 sheet. 6) ☐ Other:

Applicants' election with traverse of Group III (claims 11, 12, 16, and 24-73) and polypeptide sequence SEQ ID NO: 73 in Paper No. 10, filed 3/28/02, is acknowledged. The traversal is on the ground(s) that no showing of serious search burden has been shown with respect to inventions III and IV. This is not found persuasive because the previous office action clearly described the differing type of subject matter between these two groups. It is well known that an antibody is a recognition protein which binds via epitope recognition whereas the polypeptides of Group III do not perform in antibody recognition reactions other than as possibly antigen that is being recognized. It was noted that processing may connect inventions but that such processing such as utilizing a polypeptide in producing an antibody thereto does not negate the clear difference in activities between these two inventions, wherein a clear and serious search burden which is distinct and different exists wherein polypeptides of Group III would be searched via their activity and sequence whereas the Group IV antibodies have a completely different sequence as required for their antigen recognition function compared to what is being recognized which may be a polypeptide of Group III.

Another traversal argument is that polynucleotides and polypeptides should be searched together. In response these have been clearly characterized as separate subject matter in the

previous office action. Even if they are published together as argued by applicants the sequence for a polynucleotide and the sequence for a polypeptide is different subject matter requiring separate sequence comparison which is an added search burden over only one sequence of either of these types. It is also pointed out that the instant polypeptide sequences such as for the elected SEQ ID NO: 73 are lengthy and comparison requires massive computer searches and computation in order to even determine which polypeptides in the databases are most closely matched. Then a printout of the closely matched sequences must be read in a multi-page lengthy document in order to determine whether the claimed subject matter limitations are met for any of the sequences in said lengthy search result data output. This burdensome consideration must be performed for each and every sequence under consideration including "separately" for polypeptides and polynucleotides. It is noted that applicants have not supplied any method of performing polypeptide and polynucleotide searches together along with concurrent consideration of any potential sequence matches. They must be separately evaluated even if printed one on top of another in a publication. The above clearly documents the undue search burden if polynucleotides and polypeptides are examined together as compared to separately.

Another traversal argument is that the search for a

polypeptide would supply useful information for an antibody search and that antibodies are frequently defined by the epitopes that they define. In response the sequence, function, and/or name of a polypeptides lacks any information as to epitopes or antibodies that recognize them. Such epitope and/or antibody information must be separately described from the basic characterization of a polypeptide and thus is a separate search burden over the polypeptide per se. Additionally, a polypeptide of any significant size generally will have multiple, many numerous epitopes that are recognizable by an antibody. Thus, a major undertaking would be to describe these epitopes for any polypeptide and then compare a multitude of antibody recognition details to search antibody subject matter as claimed. The multitudinous quantity of subject matter as summarized above clearly also documents the undue search burden of an antibody invention over only a polypeptide invention.

Another traversal argument is that a search for uses of polypeptides would be overlapping with the polypeptide search. In response, this is a allegation without factual support that consideration of a polypeptide disclosure is overlapping with description of their use. In fact, these aspects of a polypeptides must be described separately, if not in the same publication then in separate ones. Applicants are reminded that consideration of a publication for a polypeptide is most commonly

a focused consideration which would not require the further reading of the details of use of the polypeptide which are separately described thus again documenting the undue search burden of searching a polypeptide invention with its uses over only the polypeptide per se.

The requirement is still deemed proper and is therefore made FINAL.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed only to 27 Human Secreted Proteins whereas in contrast the elected claims only are directed to one protein with various forms such as non-secreted forms, fragments, epitopes, etc.

#### NEW MATTER

Claims 25, 31, and 69-73 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Consideration of the specification as filed has revealed that pages 58 and 59 describe SEQ ID NO: 73 but not there or anywhere the specific truncated versions in the instant claims. These versions are therefore NEW MATTER as there is no written

basis for them as filed as set forth in the above listed claims.

#### LACK OF UTILITY

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material,

alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 11, 12, 16, and 24-73 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

The claimed polypeptides are not supported by a specific asserted utility because the disclosed uses of these compositions are not specific and are generally applicable to any polypeptide. The specification states that the polypeptide of SEQ ID NO: 73 compounds may be useful for the diagnosis and/or treatment of cancer as noted on page 59 of the instant specification. It appears that these asserted utilities are based on a specific tissue distribution of polypeptides of gene number 23. It is noted that said distribution has not been set forth in the specification so that further research would be required in order to determine what said specific distribution is as well as which of the many claimed fragments of SEQ ID NO: 73 is distributed as such. No control tissue has been defined in said discussion for

comparison. Possible assumptions as to what controls may have been tested, or not, falls short of a specific description of such controls as needed for a specific utility in currently available form. Specificity may be interpreted also in many ways. The polypeptides may be specific for certain organisms and not in others. It is noted that said page 59 discussion lacks even a definition of what organism is meant regarding tumor tissue that may be tested and/or treated with compositions of the instant invention. Thus, the statements as pointed to by applicants fall short of supporting a specific utility in currently available form. Similarly, a polypeptide may be utilized for the detection of expression, antibody production, Western blots, etc. These are non-specific uses that are applicable to proteins in general and not particular or specific to the polypeptides being claimed.

Further, the claimed polypeptides are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, the claimed polypeptides could be used in conducting research to functionally characterize the protein. The need for such research clearly indicates that the polypeptide and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted

utility in those instances where the final product is not supported by a specific and substantial utility. The research required to characterize potential polypeptide biological activities does not constitute a specific and substantial utility. Identifying and studying the properties of a polypeptide itself or the mechanisms in which the polypeptide is involved does not define a "real world" context or use. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the polypeptide compound(s) such that another non-asserted utility would be well established for the compounds.

#### LACK OF ENABLEMENT

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 12, 16, and 24-73 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility, or, alternatively, a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claims 36-63 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for , does not reasonably provide enablement for . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Claims 36-63 either directly or via dependence cite the determination of a claimed polypeptide via specific antibody

binding. Such specificity is well known to be determined by comparison to a control polypeptide. None have been set forth by which to define the conditions of specificity. Consideration the myriad of proteins and polypeptides, as well as peptide epitopes, that are known, the choice of proper control polypeptides for the specificity determination for the claims is clearly undue experimentation.

#### VAGUENESS AND INDEFINITENESS

Claims 11, 12, 16, and 36-63 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11, 12, and 16 are vague and indefinite as to what is meant therein by the limitations "variant" or "species homologue". Without some definition of the metes and bounds of these limitations, the polypeptides included therein may include any other polypeptide since no limitation of variation or homologue character would include any number of changes, deletions, and/or additions to result in any other polypeptide. Clarification of the metes and bounds of the claim is requested via clearer claim wording.

Claims 40-42 cite "the protein" of claim 36 which lacks clear antecedent basis in that only a polypeptide is cited in

claim 36. Clarification via clearer claim wording is requested. This same unclear antecedent basis exists in claims 47-49, 54-56, and 61-63.

Claims 36-63 are vague and indefinite because these claims do not define the metes and bounds of the specificity in the claims. These claims, such as claim 36 indicate specific binding to a second polypeptide but do not define what is not bound to. Is it the first polypeptide in the claims? Is it a closely related by undefined polypeptide variant or homologue? Clarification via clearer claim wording is requested.

The disclosure is objected to because of the following informalities:

In the specification on page 11 etc. single spaced text is set forth. It is noted that the specification must be set forth only in double-spaced text or 1 1/2 lines spaced text. See the MPEP at section 608.01 under PAPER REQUIREMENTS.

Appropriate correction is required.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894.

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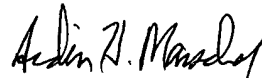
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The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 14, 2002

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER